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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/051,243	01/22/2002	Maurice Israel	033532-001	8007
7590 01/28/2008 Norman H. Stepno. Esquire			EXAMINER	
BURNS, DOANE, SWECKER & MATHIS, L.L.P.			MCINTOSH III, TRAVISS C	
P.O. Box 1404 Alexandria, VA	O. Box 1404 lexandria, VA 22313-1404		ART UNIT	PAPER NUMBER
·			1623	
			MAIL DATE	DELIVERY MODE
	,		01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<del></del>	·	Application No.	Applicant(s)			
Office Action Summary		10/051,243	ISRAEL ET AL			
		Examiner	Art Unit			
		Traviss C. McIntosh	1623			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAnsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I.  lely filed  the mailing date of this communication.  O (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 10 Oc	<u>ctober 2007</u> .				
,	•	action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.			
Dispositi	on of Claims					
5)⊠ 6)⊠ 7)□	Claim(s) 9,10 and 12-16 is/are pending in the at 4a) Of the above claim(s) is/are withdraw Claim(s) 13-16 is/are allowed.  Claim(s) 9,10 and 12 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or	vn from consideration.				
Applicati	on Papers					
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the conference of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Example 1.	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment	t(s)	_				
2) 🔲 Notice 3) 🔲 Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:	te			

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## **DETAILED ACTION**

The Amendment filed 10/10/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 13-16 have been added

Claims 1-8 and 11 have been canceled.

Remarks drawn to rejections of Office Action mailed 4/10/2007 include:

103(a) rejection over Blache and Neu et al.: which has been maintained for reasons of record.

103(a) rejection over Blache and Lechner et al.: which has been overcome by applicant's arguments and filing of a declaration and has been withdrawn.

An action on the merits of claims 9-10 and 12-16 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 103

The rejection of claims 9, 10, and 12 under 35 U.S.C. 103(a) as being unpatentable over Blache et al. (US 5,523,322) in view of Neu et al. ("Platelet aggregation and multiple sclerosis", Acta neurol. scandinav., vol. 66, pp. 497-504, 1982) is maintained for reasons of record.

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Claims 9, 10, and 12 are drawn to methods of treating various diseases or conditions associated with the excessive release of glutamate, optionally being multiple sclerosis (MS), using compounds of formula I or II.

Blache et al. teach methods of inhibiting blood-platelet aggregation with compounds of formula I or II. What they do not teach is treating MS.

Neu et al. teach that platelet aggregation occurs in MS patients (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the naphthoquinone derivatives of Blache et al. to treat MS with these references before them. The logic flows from the fact that Blache et al. teach that the compounds are capable of inhibiting platelet aggregation and Neu et al. teach that platelet aggregation occurs in MS patients. One would have been motivated to use the compounds in the methods of treating MS as the compounds are known to inhibit platelet aggregation and platelets are known to aggregate in MS patients.

Applicant's arguments filed 10/10/2007 have been fully considered but they are not persuasive. Applicants argue that Neu states MS patients showed increased drug-induced platelet aggregation and that Neu hypothesized spontaneous platelet aggregation could be demonstrated but did not show it. This is not found persuasive. Neu state on page 501 that "a strong tendency to spontaneous aggregation was seen in about 15% of the MS patients, but none in the control group". As such, Neu et al. do indeed demonstrate spontaneous platelet aggregation in MS patients. Applicants then point that Anderson describes MS treatment as of 1996 which does not address platelet aggregation. This is not seen to be convincing. Because one article fails to

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mention platelet aggregation as a possible cause of MS, or symptom associated with MS, does not negate that Neu et al. clearly show platelet aggregation occurs in MS patients. Neu clearly state that "an increased tendency to spontaneous aggregation of blood platelets of MS patients could also be demonstrated" (page 501 – discussion). Neu continues with "All authors found an increased adhesiveness of the blood platelets together with a regular correlation between the extent of increased adhesiveness and the activity of the disease process." Neu even concludes their paper with the following: "if these results were to be confirmed in a greater number of MS patients, then, in our opinion, it would be justified to use inhibitors of platelet aggregation in an attempt to treat patients with MS". Thus, it is very clear that platelet aggregation inhibitors are indeed taught to at least be tried to be used as therapeutics for MS patients. Thus, one cannot overlook this teaching in the art, regardless of what other references teach as successful MS therapeutics, as this reference clearly demonstrates platelet aggregation inhibitors can be used, or

## Conclusion

Claims 13-16 are allowed.

can be tried to be used, in MS therapy.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh January 22, 2008 Shaojia A. Jiang

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Supervisory Patent Examiner